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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,283	06/14/2001	Robert J. Crowley	BSC-031CN	7430
21323	7590	01/26/2005	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP			JUNG, WILLIAM C	
HIGH STREET TOWER			ART UNIT	
125 HIGH STREET			PAPER NUMBER	
BOSTON, MA 02110			3737	

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b> 09/881,283	<b>Applicant(s)</b> CROWLEY, ROBERT J.	
	<b>Examiner</b> William Jung	<b>Art Unit</b> 3737	

-- **Th MAILING DATE of this communication appears on the cov r sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.  
 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-17, 20-24, 26-32, 44-47, 50-63 and 66-88 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-4, 7-17, 20-24, 26-32, 44-47, 50-63, 66-74, 81, 87 and 88 is/are rejected.  
 7) ☒ Claim(s) 75-79 and 81-86 is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1-4, 7-17, 20-24, 26-32, 44-47, 50-63, and 66-88 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 8-10, 12, 13, 44, 51-53, and 56 are rejected under 35 U.S.C. 102(a) as being anticipated by *Whitehead et al* (US 6,201,989 B1).

**Claims 1, 8, 44, and 51:** Whitehead et al anticipates all claimed features in claims 1 and 44. Whitehead et al disclose a method and apparatus where an in-vivo or insertable device having a light source 122 to generate light with an array of optical probe 120 to detect light generated by light source 122. The light source and the probe array are housed within a frame 112. The probe is designed to detect optical properties of the reflected light from a surrounding tissue when placed or inserted within a body (col. 14, lines 410-60; figure 15).

**Claims 9, 10, 52, and 53:** The materials in which the frame or housings are made to not have function for the purpose of optical imaging or sensing. Therefore, the molded or foraminous material for the frame is a design choice.

**Claims 12 and 13:** Whitehead et al disclose in figures 11 and 12 where the catheter includes optical lens and mirror 90 to focus the optical light.

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**Claim 56:** Whitehead et al illustrate in figure 4 that the transmitted/received signals via fiber 26 from a tissue is processed as an electrical signal.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 2, 3, 45, 46, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Whitehead et al* as applied to claims 1 and 44 above, and further in view of *Hunter et al* (US 5,716,981).

Whitehead et al substantially disclose of all claimed features in claims 2, 3, 45, 46, and 50. However, Whitehead et al's disclosure does not include oligonucleotide or protein bounded to the probe. Hunter et al teach that oligonucleotide or protein on substrate can be detected via radiation path, similar to radiation detection with substrate attached to a probe described by Kovac et al. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to adapt Hunter al's teaching of using oligonucleotide or protein substrate to detect radiation signal.

6. Claims 4, 7, 11, 14, 15, 17, 20-23, 26, 31, 32, 47, 54, 55, 57, 59-63, 66-69, 71, 80, 87, and 88 rejected under 35 U.S.C. 103(a) as being unpatentable over *Whitehead et al* as applied to claims 1 and 44 above, and further in view of *Kovacs et al* (US 5,833,603).

Whitehead et al substantially disclose of all claimed features in claims 4, 7, 11, 14, 15, 17, 20-23, 26, 31, 32, 47, 54, 55, 57, 59-63, 66-69, 71, 80, 87, and 88. However, Whitehead et al have deficiency in the followings, which are disclosed by Kovac et al.

**Claims 4, 31, 32, 47, 54, 55, 57, 59-63, 66-69, 71, and 80:** Kovac et al disclose an implantable biosensing transponder including substrate, 40 (figure 1), excitation source capable of generating radiation in a form of an optical emitter (col. 10, lines 28-45, probe in a form of a dye filled member, in path of radiation, probe contact a fluorescently-labeled analyte, such as tissue, blood, or cerebrospinal fluid, as in 4 (figure 3, element 56 and col. 10, lines 3-28). In addition, the biosensor transponder includes detector for detecting optical property of the probe to convert detected optical signals to electric signals in a form of photosensors (col. 10, line 49). The housing or capsule 44 house the excitation source, probe, and detector (col. 10, lines 24-26).

**Claim 11:** Kovac et al's apparatus also includes optics that affects the path of the radiation via lens (col. 13, lines 10-16).

**Claims 14 and 15:** Kovac et al's apparatus also includes processor to process the detected signals and amplifier to amplified the detected signals (col. 13, lines 5-15; col. 16, line 5).

**Claims 7, 17, and 20-23:** Kovac et al's apparatus also includes spectrometer and LED encapsulated in transparent housing with LED source providing wavelength within 250-1100nm range (col. 11, lines 48-50; col. 12, line 40). Furthermore, Kovac et al's apparatus includes Photodiode and light detection system capable of detecting light at multiple wavelengths (col. 11, lines 55-65).

**Claims 26, 87, and 88:** Kovac et al 's apparatus is a catheter that carries the body insertable device to an area of interest, such as guidewire (figure 12, col. 18, lines 15-35).

Kovac et al's teachings above illustrate advantages of various in-vivo optical imaging and biosensing device and techniques to improve upon Whitehead et al's invention. Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovac et al's teachings to Whitehead et al to improve the optical imaging and sensing device and method.

7. Claims 16 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Whitehead et al* as applied to claims 1 and 44 above, and further in view of *Salb* (US 5,408,996).

Whitehead et al substantially disclose of all claimed features in claims 16 and 58, in addition to description above includes a transmission of detected signals to a remote reader (col. 6, lines 55-56) except that Whitehead et al do not teach a display. However, it is well known in the art to one having an ordinary skill in the art of medical imaging to have display so one may observe diagnostic data image captured from the imaging apparatus. For example, Salb teaches a tissue diagnostic device wherein captured data from an optical detector is transmitted to a display.

8. Claims 24 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Whitehead et al* and *Kovacs et al* as applied to claims 1, 23, 44, and 69 above, and further in view of *McGill et al* (US 5,412,087).

Whitehead et al and Kovac et al substantially disclose of all claimed features in claims 24 and 70, in addition to description above includes a filter (col. 5, line 25). However, Whitehead et al and Kovac et al do not specifically disclose the filter as a band pass filter (BPF). McGill et al teach an analyte biosensor that uses a BPF (col. 14, line 30). Therefore it would have been

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obvious to one having an ordinary skill in the art at the time the invention was made adapt McGill et al's teaching of using BPF to detected optical signal to improve the reduction of noise.

9. Claims 27-30, 72, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Whitehead et al* as applied to claims 1 and 44 above, and further in view of *Pizziconi et al* (US 4,832,034).

Whitehead et al substantially disclose of all claimed features in claims 27, 29, 72, and 74 in addition to description above includes insertable catheter. However, Whitehead et al do not anticipate the catheter with a lumen capable of withdrawing biosensing fluids for analysis. Pizziconi et al teach such a feature, in which filtrate is withdrawn from the body and placing it in contact with the sensors (col. 15, line 50). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to adapt Pizziconi et al's withdrawal of biosensing material for further analysis to improve Whitehead et al's device.

#### ***Allowable Subject Matter***

10. Claims 75-79 and 81-86 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739. The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*WC*  
January 20, 2005

  
**BRIAN L. CASLER**  
**SUPERVISORY PATENT EXAMINER**  
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